

1. Amendment

1.1 IN THE CLAIMS:

1. (Currently Amended) An isolated polynucleotide that:
  - (a) encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and that comprises an at least 27 contiguous amino acid sequence from SEQ ID NO:2 ~~or SEQ ID NO:4;~~ or
  - (b) encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 85% sequence identity with the amino acid sequence of SEQ ID NO:2 ~~or SEQ ID NO:4;~~ or
  - ~~(c) comprises an at least 26 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3; or~~
  - ~~(d) hybridizes to the sequence of SEQ ID NO:1 or SEQ ID NO:3, or to the complement thereof, under stringent hybridization conditions.~~
2. (Currently Amended) The isolated polynucleotide of claim 1, comprising a sequence region that encodes a polypeptide having an at least 27 contiguous amino acid sequence from SEQ ID NO:2 ~~or SEQ ID NO:4.~~

3. (Currently Amended) The isolated polynucleotide of claim 2, comprising a sequence region that encodes a polypeptide having an at least 29 contiguous amino acid sequence from SEQ ID NO:2-~~or SEQ ID NO:4~~.
4. (Currently Amended) The isolated polynucleotide of claim 3, comprising a sequence region that encodes a polypeptide having an at least 31 contiguous amino acid sequence from SEQ ID NO:2-~~or SEQ ID NO:4~~.
5. (Currently Amended) The isolated polynucleotide of claim 4, comprising a sequence region that encodes a polypeptide having an at least 33 contiguous amino acid sequence from SEQ ID NO:2-~~or SEQ ID NO:4~~.
6. (Currently Amended) The isolated polynucleotide of claim 5, comprising a sequence region that encodes a polypeptide having an at least 35 contiguous amino acid sequence from SEQ ID NO:2-~~or SEQ ID NO:4~~.
7. (Currently Amended) The isolated polynucleotide of claim 6, comprising a sequence region that encodes a polypeptide having an at least 37 contiguous amino acid sequence from SEQ ID NO:2-~~or SEQ ID NO:4~~.
8. (Currently Amended) ~~An The~~ isolated polynucleotide ~~of claim 7,~~ comprising a sequence region that encodes a polypeptide comprising ~~having~~ the sequence of SEQ ID NO:2-~~or SEQ ID NO:4~~.
9. (Currently Amended) The isolated polynucleotide of claim 1, comprising a sequence region that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 85% sequence identity with the amino acid sequence of SEQ ID NO:2-~~or SEQ ID NO:4~~.

10. (Currently Amended) The isolated polynucleotide of claim 9, comprising a sequence region that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 90% sequence identity with the amino acid sequence of SEQ ID NO:2 ~~or SEQ ID NO:4~~.
11. (Currently Amended) The isolated polynucleotide of claim 10, comprising a sequence region that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 95% sequence identity with the amino acid sequence of SEQ ID NO:2 ~~or SEQ ID NO:4~~.
12. (Currently Amended) The isolated polynucleotide of claim 11, comprising a sequence region that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 96% sequence identity with the amino acid sequence of SEQ ID NO:2 ~~or SEQ ID NO:4~~.
13. (Currently Amended) The isolated polynucleotide of claim 12, comprising a sequence region that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 98% sequence identity with the amino acid sequence of SEQ ID NO:2 ~~or SEQ ID NO:4~~.
14. (Withdrawn) The isolated polynucleotide of claim 1, comprising an at least 26 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
15. (Withdrawn) The isolated polynucleotide of claim 14, comprising an at least 30 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
16. (Withdrawn) The isolated polynucleotide of claim 15, comprising an at least 40 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.

17. (Withdrawn) The isolated polynucleotide of claim 16, comprising an at least 50 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
18. (Withdrawn) The isolated polynucleotide of claim 17, comprising the nucleotide sequence of SEQ ID NO:1 or SEQ ID NO:3.
19. (Withdrawn) The isolated polynucleotide of claim 1, comprising a sequence region that hybridizes to the sequence of SEQ ID NO:1 from about position 254 to about position 1735, or to the sequence of SEQ ID NO:3, or to the complement of SEQ ID NO:1 or SEQ ID NO:3, under stringent hybridization conditions.
20. (Withdrawn) The isolated polynucleotide of claim 19, comprising a sequence region that hybridizes under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
21. (Withdrawn) An isolated polynucleotide that comprises:
  - (a) a sequence region that consists of at least 26 contiguous nucleotides that have the same sequence as, or are complementary to, at least 26 contiguous nucleotides of SEQ ID NO:1 or SEQ ID NO:3; or
  - (b) a sequence region of from 26 to about 10,000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
22. (Withdrawn) The isolated polynucleotide of claim 21, comprising a sequence region that consists of at least 26 contiguous nucleotides that have the same sequence as, or are complementary to, at least 26 contiguous nucleotides of SEQ ID NO:1 or SEQ ID NO:3.

23. (Withdrawn) The isolated polynucleotide of claim 22, wherein said polynucleotide is from about 100 to about 10,000 nucleotides in length.
24. (Withdrawn) The isolated polynucleotide of claim 23, wherein said nucleic acid segment is from about 500 to about 5,000 nucleotides in length.
25. (Withdrawn) The isolated polynucleotide of claim 24, wherein said nucleic acid segment is from about 1000 to about 4,000 nucleotides in length.
26. (Withdrawn) The isolated polynucleotide of claim 21, comprising a sequence region of from 26 to about 10,000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
27. (Withdrawn) The isolated polynucleotide of claim 26, comprising a sequence region of from 30 to about 5000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
28. (Withdrawn) The isolated polynucleotide of claim 27, comprising a sequence region of from 40 to about 4000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
29. (Withdrawn) The isolated polynucleotide of claim 28, comprising a sequence region of from 50 to about 3000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under

hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.

30. (Withdrawn) The isolated polynucleotide of claim 29, comprising a sequence region of from 60 to about 2000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
31. (Withdrawn) The isolated polynucleotide of claim 30, comprising a sequence region of from 70 to about 1000 nucleotides in length that hybridizes to the nucleic acid segment of SEQ ID NO:1 or SEQ ID NO:3; or that hybridizes to the complement thereof, under hybridization conditions comprising a salt concentration of from about 0.02 M to about 0.15 M, and a temperature of from about 50°C to about 70°C.
32. (Withdrawn) The polynucleotide of claim 1 or claim 21, further defined as an RNA, a PNA, or a DNA segment.
33. (Withdrawn) The polynucleotide of claim 1 or claim 21 comprised within a vector.
34. (Withdrawn) The polynucleotide of claim 33, comprised within a plasmid, cosmid, phage, phagemid, baculovirus, virus, virion, bacterial artificial chromosome, or yeast artificial chromosome vector.
35. (Withdrawn) The polynucleotide of claim 34, wherein said vector further comprises a promoter that is operably linked to said polynucleotide.
36. (Withdrawn) The polynucleotide of claim 35, wherein said promoter is a heterologous promoter.

37.-38. (Canceled)

39. (Currently Amended) A virus comprising the polynucleotide of claim 1 ~~or claim 21~~.

40. (Currently Amended) A host cell comprising the polynucleotide of claim 1 ~~or 21~~ or the virus of claim 39.

41. (Previously Presented) The host cell of claim 40, wherein said host cell is a bacterial cell.

42. (Previously Presented) The host cell of claim 41, wherein said host cell is an *Escherichia*, *Salmonella* or *Agrobacterium* cell.

43.-76. (Canceled)

77. (Previously Presented) The isolated polynucleotide of claim 7, comprising a sequence region that encodes a polypeptide having an at least 40 contiguous amino acid sequence from SEQ ID NO:2.

78. (Previously Presented) The isolated polynucleotide of claim 77, comprising a sequence region that encodes a polypeptide having an at least 60 contiguous amino acid sequence from SEQ ID NO:2.

79. (Previously Presented) The isolated polynucleotide of claim 78, comprising a sequence region that encodes a polypeptide having an at least 80 contiguous amino acid sequence from SEQ ID NO:2.

80. (Previously Presented) The isolated polynucleotide of claim 79, comprising a sequence region that encodes a polypeptide having an at least 100 contiguous amino acid sequence from SEQ ID NO:2.
81. (Previously Presented) The isolated polynucleotide of claim 80, comprising a sequence region that encodes a polypeptide having an at least 120 contiguous amino acid sequence from SEQ ID NO:2.
82. (Previously Presented) The isolated polynucleotide of claim 81, comprising a sequence region that encodes a polypeptide having an at least 140 contiguous amino acid sequence from SEQ ID NO:2.
83. (Previously Presented) The isolated polynucleotide of claim 82, comprising a sequence region that encodes a polypeptide having an at least 160 contiguous amino acid sequence from SEQ ID NO:2.
84. (Withdrawn) The isolated polynucleotide of claim 1, comprising an at least 100 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
85. (Withdrawn) The isolated polynucleotide of claim 84, comprising an at least 120 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.



86. (Withdrawn) The isolated polynucleotide of claim 85, comprising an at least 140 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
87. (Withdrawn) The isolated polynucleotide of claim 86, comprising an at least 160 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
88. (Withdrawn) The isolated polynucleotide of claim 87, comprising an at least 180 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
89. (Withdrawn) The isolated polynucleotide of claim 88, comprising an at least 200 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
90. (Withdrawn) The isolated polynucleotide of claim 89, comprising an at least 220 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
91. (Withdrawn) The isolated polynucleotide of claim 90, comprising an at least 240 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
92. (Withdrawn) The isolated polynucleotide of claim 91, comprising the nucleotide sequence of SEQ ID NO:1.
93. (Withdrawn) The isolated polynucleotide of claim 91, comprising the nucleotide sequence of SEQ ID NO:3.

94. (Previously Presented) An isolated polynucleotide that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and that comprises an at least 27 contiguous amino acid sequence from SEQ ID NO:2.
95. (Previously Presented) An isolated polynucleotide that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and at least about 85% sequence identity with the amino acid sequence of SEQ ID NO:2.
96. (Withdrawn) An isolated polynucleotide that encodes a polypeptide having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity, wherein said polynucleotide comprises an at least 26 contiguous nucleotide sequence from SEQ ID NO:1 or SEQ ID NO:3.
97. (Withdrawn) An isolated polynucleotide that hybridizes to the sequence of SEQ ID NO:1 or SEQ ID NO:3, or to the complement thereof, under stringent hybridization conditions.
98. (Previously Presented) An isolated polynucleotide comprising a sequence region that encodes a polypeptide having the sequence of SEQ ID NO:2.

## **2. RESPONSE**

### **2.1 STATUS OF THE CLAIMS**

*Applicants appreciate the Examiner's voluntary invocation of Rule 126 to facilitate correction of the clerical error resulting in the misnumbering of claims 20-77 as originally filed. Applicants note that these claims have been renumbered 19-76, and prosecution continues based upon the renumbered original claims.*

*Claims 1-36, 39-42, and 77-98 (as renumbered) were pending at the time of the action.*

*Claims 14-36, 84-93, and 96-97 are canceled without prejudice and without disclaimer, as being drawn to non-elected inventions.*

*Claims 1-13, and 39-40 have been amended herein.*

*Claims 1-13, 39-42, and 77-83, 94-95, and 98 (as renumbered), are therefore now pending in the case.*

Applicants note for the record that no rejections were entered for the pending claims, under 35 U. S. C. § 102, or 35 U. S. C. § 103, and as such, affirm the Examiner's position that the claims were free from any prior art concerns. Likewise, Applicants note for the record, and affirm the Examiner's position that no utility rejections under 35 U. S. C. § 101 exist for any of the pending claims.

### **2.2 SUPPORT FOR THE CLAIMS**

Complete support for each of the claims as amended herein is provided by the specification and original claims as filed. Applicants certify that no new matter has been introduced as a result of the accompanying amendment.

**2.3 THE OBJECTION TO CLAIMS 1-13 AND 39-42 IS OVERCOME**

*Claims 1-13 and 39-42 were objected to for reciting limitations drawn to non-elected inventions.*

*Applicants respectfully traverse. However, solely in the interest of proceeding certain commercially relevant embodiments of the invention to speedy allowance, mindful of patent term considerations, and solely to facilitate expeditious examination of the pending claims, Applicants have amended the claim language to focus upon polynucleotide species that encode polypeptides that comprise amino acid sequences obtained from SEQ ID NO:2. Applicants reserve the right to re-file the non-elected claims without prejudice in a continuing application.*

In light of the foregoing, Applicants now respectfully request that the objection be withdrawn.

**2.4 THE REJECTIONS UNDER 35 U. S. C. § 112, 1<sup>ST</sup> PARAGRAPH, ARE OVERCOME**

*Claims 1-7 and 9-13 and 39-42, 77-83, and 94-95 were rejected under 35 U. S. C. §112, 1<sup>st</sup> paragraph, (a) allegedly for containing subject matter which was not described in the specification in such as way as to enable one of skill in the art to make and/or use the invention; and (b) because the Specification allegedly is enabling only for a spinach PEAMT sequence (SEQ ID NO:2).*

Applicants respectfully traverse each of these rejections.

Although Applicants contest the rejection as applied to claims 1-7, 9-13, and 39-42, the indication of subject matter already agreed to be fully enabled (e.g., the subject matter of claim

8) is appreciated. In fact, the indication that claim 8 is fully enabled compels a finding of adequate enabling support for at least certain of the rejected claims.

The rejection of these claims appears to rest on the allegation that the specification does not reasonably enable all DNA segments that encode polypeptides having *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase activity and that have at least about 27 contiguous amino acids in common with the recited species (SEQ ID NO:2).

The Final Action appears not to have considered Applicants' lengthy response to the previous Action which rejected the relevant claims for essentially the same reasons. As it was pointed out previously, the Office has also apparently overlooked the practical requirements of utility and enablement. Any practical usefulness is sufficient to satisfy the utility requirement of § 101 and the "how to use" requirement of § 112, first paragraph. *Cross v. Iizuka*, 224 USPQ 739, 748 (Fed. Cir. 1985); *In re Brana*, 34 USPQ 2d 1436 (Fed. Cir. 1995).

The claimed DNA segments have numerous practical uses outside recombinant expression, and outside the production of enzymatically-active proteins. For example, these polynucleotides find particular use in various hybridization and cloning embodiments. Where the polynucleotides segments are used in recombinant expression, there is absolutely no requirement that the expressed protein or polypeptide be enzymatically active. The requirements are only that a skilled artisan be able to make and use the DNA segments without undue experimentation (§ 112, first paragraph) and that the product have some practical utility (§ 101).

The Action does not question the ability of an artisan to practice recombinant expression techniques, so the § 112 requirement is clearly met. Likewise, claims directed to polynucleotides that encode *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase-derived peptides and or proteins, also meet the § 101/§ 112 requirements, because such peptides and

polypeptides (as well as the polynucleotides encoding them) may be used in various embodiments that do not require *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase enzymatic activity. For example, the Specification notes on pages 11 bridging to 12 that various uses for *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase proteins/peptides lacking enzymatic activity, including for example, as controls in activity studies; to bind and purify counterpart *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase-specific antibodies; to generate *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase-specific peptide epitopes, to immunize animals to produce *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase-specific antibodies, and to purify proteins that interact with *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase-derived peptides, polypeptides, or proteins, among other things.

Moreover, the Specification exhaustively teaches how to make and use such *S*-adenosyl-L-methionine:phosphoethanolamine *N*-methyltransferase compositions in a variety of *in vivo* and *in vitro* embodiments, including the generation of recombinant host cells and transgenic plants that comprise one or more of the claimed polynucleotide compositions. In fact, from page 12 to page 33, there is extensive written description on using the claimed polynucleotides in a variety of embodiments. Importantly, any experimentation required in the practice of these embodiments, would thus be confined to very routine matters of protein and antibody production and the use of such compositions in functional assays or cell transformation experiments, each of which is described at length in the specification.

Should any experimentation be necessary, it would certainly not rise to the level of "undue experimentation". In assessing the question of whether undue experimentation would be required,

the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (C. C. P. A. 1976). The need for some experimentation does not render the claimed invention unpatentable under 35 U. S. C. § 112, 1<sup>st</sup> paragraph. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*.

The issue in this case is similar to that decided by the Federal Circuit in *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) (although any experimentation in the present case should be less than in *Wands*). In *Wands*, the P.T.O. took the position that the applicant failed to demonstrate that the disclosed biological processes of immunization and antibody selection could reproducibly result in a useful biological product (antibodies from hybridomas) within the scope of the claims. In its decision overturning the P.T.O.'s rejection, the Federal Circuit found that Wands' demonstration of success in four out of nine cell lines screened was sufficient to support a conclusion of enablement. The court emphasized that the need for some experimentation requiring, *e.g.*, production of the biological material followed by routine screening, was not a basis for a finding of non-enablement, stating:

"Disclosure in application for the immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring 'undue experimentation,' even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or 'hybridomas,' since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one 'experiment' is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired antibodies is not excessive, in view of Applicants' success in each attempt to produce antibody that satisfied all claim limitations."

8 U.S.P.Q.2d at 1400.

The parallels between *Wands* and the present case are striking. Practice of the presently claimed invention does not require undue experimentation, even though the production of various polynucleotides and/or polypeptides "may" require screening to confirm activity, or may involve comparing the DNA or protein sequence of a candidate species to those sequences disclosed, for example, in SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, and/or SEQ ID NO:4. Practitioners in the art routinely conduct functional screening assays and DNA and protein sequence determination and comparison. Such comparisons and determinations, clearly is not undue experimentation.

In summary, Applicants again confirm that the "make and use" requirement and the specific written description requirement for the claimed polynucleotide species have been satisfied, and the breadth of the working examples is entirely commensurate with the scope of the claims. Therefore, the 35 U. S. C. § 112, 1<sup>st</sup> paragraph rejection as a whole is overcome, and should be withdrawn. Applicants respectfully solicit the Examiner's concurrence with same, and request that the rejection be withdrawn.

**2.5 THE REJECTIONS UNDER 35 U. S. C. § 112, 2<sup>ND</sup> PARAGRAPH, HAVE BEEN OVERCOME**

***Claims 9 to 13 and 95 have been rejected under 35 U. S. C. §112, 2<sup>nd</sup> paragraph, as being indefinite as allegedly failing to particularly point out and claim the subject matter that Applicants regard as their invention.***

The Action rejects claims 9-13 and 95 as allegedly being indefinite in light of the "at least about" language in the claims, which the Examiner contends is a relative term that renders the claims indefinite. Applicants respectfully traverse. The use of both "relative terms" and particular claim language including the word "about" is perfectly acceptable under the law.



Applicants again respectfully point out that the Action has not actually set forth any reasoning to support the rejection. The rejection is thus *prima facie* improper. Applicants further respectfully point out that the rejection is at odds with long-established examination practice and case law and is therefore unsustainable.

Applicants have again examined the relevant portions of M. P. E. P. § 2173, concerning the criteria for assessing compliance with 35 U. S. C. § 112, second paragraph, and can find nothing to indicate that the present claims are indefinite by the use of terms including the phrase "at least about" (such as "at least about 85%," "at least about 95%", *etc.*). In fact, this section of the M. P. E. P. provides that Applicants can "define in the claims what they regard as their invention essentially in whatever terms they choose so long as the terms are not used in ways that are contrary to accepted meanings in the art" (M. P. E. P. § 2173.01, at page 2100-145, column 2). Clearly the term "about" in these claims is not used in a manner contrary to its ordinary meaning, and these claims are sufficiently definite and the rejection should be withdrawn.

M. P. E. P. § 2173.05 provides that claim language including "terms of degree" does not automatically render the claim indefinite. Rather, terms of degree are acceptable so long as one of ordinary skill in the art would be apprised of the scope of the claim. In order to determine whether a skilled artisan would understand a term of degree presented in a claim, this section of the MPEP indicates that the specification should be assessed in regard to the provision of "some standard for measuring that degree". Should such a standard be provided, the claims meet the requirements of 35 U. S. C. § 112, 2<sup>nd</sup> paragraph.

Only where the specification does not provide some standard for measuring the degree of a relative term, would a further inquiry be required. Even in such circumstances,

M. P. E. P. § 2173.05 explains that the clarity requirements can still be met so long as one of ordinary skill in the art would nevertheless be reasonably apprised of the scope of the invention in view of the knowledge in the art. In fact, M. P. E. P. § 2173.05(b) specifically exemplifies that the term “about” is definite unless there is close prior art, or nothing in the specification, prosecution history, or prior art, to provide any indication as to what range the term “about” is applied to. In the present case, however, both the detailed standards for measurements set forth in the specification and the knowledge existing in the art support the definiteness of the pending claims.

For example, in rejected claim 9, the term “at least about 85% sequence identity”, the word “about” is used both according to its ordinary dictionary definition and the common understanding in the biotechnological arts. Scientifically, one of ordinary skill in the art would understand the term “about 85%”, as used in the claims and specification, to refer to its ordinary meaning, for example, “approximately 85%” (see the Specification at page 5, 12, and 16-20) would be understood to encompass those sequences that are approximately 85% identical, to the recited sequence. Likewise, it would be clear to one of ordinary skill in the art that the term “about 95%”, as used in the claims and specification, would also refer to its ordinary meaning, that is, sequences that are “approximately 95%” identical to the claimed sequence.

Finally, Applicants again note for the record that the rejected claim language has been used extensively in the molecular biology art units, and particularly when describing “at least about XX%” sequence identity or homology in amino acid and/or polynucleotide inventions. In fact, a search of the patent database reveals no less than four-dozen patents have been issued within the past 4 years that employ this specific language (see *e.g.*, U. S. Patents 6,359,197

[claims 1 and 3]; 6,388,052 [claims 17 and 18]; 6,372,475 [claims 1 and 2]; 6,365,364 [claim 1]; and 6,087,122 [claims 1 to 3], *etc.*).

Applicants believe that the pending claims are fully definite and do not lack clarity as required by this section of the Statute. As such, Applicants respectfully request that the rejection be withdrawn.

## **2.6 REQUEST FOR CONTINUED EXAMINATION (RCE) UNDER 37 C. F. R. § 1.114 AND LIMITED SUSPENSION UNDER 37 C. F. R. § 1.103(C)**

The present RCE is filed within the statutory period after giving Notice of Appeal and is timely in light of the enclosed request for extension of time and fees. Pursuant to 37 C. F. R. § 1.103(c), Applicants have also requested a 90-day deferral to facilitate the following request for Examiner interview.

## **2.7 REQUEST FOR EXAMINER INTERVIEW**

Pursuant to M. P. E. P. § 713.01 and 37 C. F. R. § 1.133, Applicants hereby request the scheduling of an Interview with Examiner McElwain and Applicants' undersigned representative, Dr. Mark D. Moore, to discuss the pending claims as are now in condition for allowance, and to address any particular remaining issues in the mind of the Examiner in charge of the case, once she has had the opportunity to review this response and accompanying amendment.

Applicants' undersigned representative will contact Examiner McElwain to arrange such interview within the next 30 days. In order that Applicants have sufficient time to address any remaining issues following the conclusion of such an interview, Applicants' new representative

has also submitted a 90-day deferral request herewith, pursuant to 37 C. F. R. § 1.103(c), as well as a Request for Continuing Examination pursuant to 37 C. F. R. § 1.114, to facilitate the continued prosecution of the pending claims on the merit after entry of the final office action.

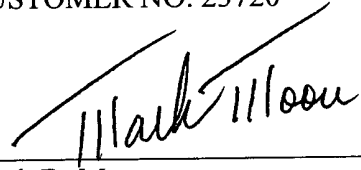
## 2.8 CONCLUSION

Applicants believe this to be a full, timely and complete response to the outstanding Final Action, and further believe that all pending claims are free of any rejection under the statutes, and that the claims are now placed in condition for allowance through the entry of the accompanying amendment and consideration of the foregoing remarks.

Applicants expressly reserve the right to re-file claims directed to the remaining embodiments of the invention in subsequent continuing applications. Should the Examiner have any questions concerning the accompanying amendment, response and related papers, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

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